National Children's Study Assembly Meeting
Breakout Session: Neurodevelopmental Outcomes
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Omni Shoreham Hotel
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This meeting was held in conjunction with the National Children's Study, which is led by a consortium of federal agency partners: the U.S. Department of Health and Human Services (DHHS) (including the National Institute of Child Health and Human Development [NICHD] and the National Institute of Environmental Health Sciences [NIEHS], two parts of the National Institutes of Health, and the Centers for Disease Control and Prevention [CDC]), and the U.S. Environmental Protection Agency (EPA).

Co-Chair: Marshalyn Yeargin-Allsopp, M.D., Member, Interagency Coordinating Committee; Medical Epidemiologist, National Center on Birth Defects and Developmental Disabilities, CDC, DHHS

Co-Chair: Ruth A. Brenner, M.D., M.P.H., Director, Protocol Development, National Children's Study Program Office, National Institute of Child Health and Human Development, NIH, DHHS

Invited Participant: David J. Schonfeld, M.D., Division of Developmental Disabilities, Cincinnati Children's Hospital Medical Center; Member, Federal Advisory Committee

Invited Participant: Virginia Rauh, Sc.D., M.S.W., Columbia Center for Children's Environmental Health, Heilbrunn Center for Population and Family Health, Columbia University Mailman School of Public Health

Welcome, Introductions, and Purpose of Session

Marshalyn Yeargin-Allsopp, M.D., Member, Interagency Coordinating Committee; Medical Epidemiologist, National Center on Birth Defects and Developmental Disabilities, CDC, DHHS

Dr. Yeargin-Allsopp welcomed breakout session participants and introduced herself and the other presenters for the session. She presented the goals of the session:

- To review general principles in measurement and instrument selection for monitoring the neurodevelopmental and psychosocial status of Study participants
- To provide an overview of neurodevelopmental measures and timing for the Study
- To review "Lessons Learned" from the Children's Environmental Health Studies.

Dr. Yeargin-Allsopp reviewed the agenda for the session and noted that participants could see the related poster in the poster session that would follow.

Overview of Concepts Related to Measurement

David J. Schonfeld, M.D., Division of Developmental Disabilities, Cincinnati Children's Hospital Medical Center; Member, Federal Advisory Committee

Dr. Schonfeld discussed principles in measurement and instrument selection for monitoring neurodevelopmental and psychosocial status—issues to consider and challenges to overcome.

The Study will be following a large number of subjects over a long period of time; therefore several challenges come from that:

- Instruments need to be efficient, easy to administer, well accepted, and validated for different populations.
- Measures used commonly are preferable; some new measures can be included but should not be the sole means of assessing a critical domain; some duplicate measures can be useful for triangulation of data.
- New instruments may be added as new conditions are identified and new technology/instruments become available over the course of the Study.

The Study is aiming to provide a comprehensive assessment of neurodevelopmental and psychosocial functioning. Therefore, the Study will need to:

- Specify *a priori* key domains—for example, social development, motor skills
- Test domains at ages most likely to detect relevant and likely deficits/variance, utilizing measures sensitive to these changes
- Utilize instruments sensitive to subtle, preclinical deficits or dysfunctions, followed up with well-validated diagnostic evaluations for those who screen positive
- Withhold measuring domains or variables unlikely or less likely to provide clinically relevant information.

Dr. Schonfeld noted that the Study is taking a broad, ecological perspective—a major strength, but also a major challenge.

- Children are part of families, neighborhoods, larger communities, ethnic/cultural groups, regions/cities/states, and so forth. Measures at each level will be required.
- It is challenging to obtain valid measures for community-based measures. Obtaining such measures will require community outreach and will be costly in time, money and personnel.
- The same level of scientific scrutiny and rigor should be applied to group and community-level measures as to biological and environmental specimen measures.

Dr. Schonfeld's next point was that child development is not fixed. One instrument cannot measure one domain over the full age spectrum; therefore the Study will need to:

- Select instruments that can be applied to the widest age range and spectrum of skills
- Identify a sequential battery of instruments to measure comparable domains over the age/ability spectrum.

Some domains may only be measured at discrete time periods.

Dr. Schonfeld added that the social context is also not fixed:

- Many families will change size and structure; children will switch schools; communities change over time, and so on. It will be a challenge to control for nesting because these nested units will not be stable.
- Collection of community-level data will be more dramatically impacted by mobility than individual-level data. Dr. Schonfeld asked participants to imagine that New Orleans had been a Vanguard Center site that had already begun enrollment and what would have been required to follow up those children.
- It will be best to identify community-based measures that already are, or can be readily, incorporated into other national efforts.

Discussion

Participants asked or commented about the following issues:

- *The need for measures at multiple levels of nesting,* Dr. Schonfeld said there was discussion of measures of school environment, for example, and that the Study would need to develop measures of community influences on child development. At each level of nesting, some type of measure would be needed to take into account that nesting variable. He noted that these are very complicated issues and important variables.

- *The Hawthorne effect, in which children may change their lives as a result of being identified as members of the Study.* Dr. Schonfeld said that this was definitely a phenomenon and there is no easy way to control for it.

- *Whether the Study is looking at social outcomes, such as early pregnancy, incarceration, and criminal records.* Dr. Yeargin-Allsopp replied that the Study had an active Social Environment Working Group that studied these issues extensively and produced many recommendations, white papers, and workshops. All of these products are available on the Study Web site. The findings will be incorporated into the protocol as much as possible, and some of the recommendations and information generated may be applied in some of the adjunct studies.

Overview of Measurements of Child Development

Ruth A. Brenner, M.D., M.P.H., Director, Protocol Development, National Children's Study Program Office, National Institute of Child Health and Human Development, NIH, DHHS

Dr. Brenner summarized basic Study concepts, opportunities, and challenges:

- The Study will provide an opportunity to examine developmental trajectories and specific conditions.
- The Study presents a number of challenges:
  - Identification of measurements that are feasible
  - Comparability of measurements over the lifespan
  - Applicability of measurements in diverse populations and diverse settings.

She noted that the Study is hypothesis driven with primary outcomes related to child health and development. Framing hypotheses must:

- Be important questions regarding child health and development
- Require and be measurable with a sample of ~100,000.

In addition, costly elements must be linked to specific hypotheses.

Many of the hypotheses include outcomes related to neurocognitive, social-emotional, motor, or sensory development. Dr. Brenner highlighted examples of hypotheses:

- Prenatal infection and mediators of inflammation are risk factors for neurodevelopmental disabilities, such as cerebral palsy and autism.
- Low-level exposure to nonpersistent pesticides *in utero* (or postnatally) increases risk of poor performance on neurobehavioral and cognitive examinations during infancy and later in childhood, among those with genetically decreased paraoxonase activity.

Dr. Brenner briefly discussed sample size considerations and presented a chart showing the sample size needed to detect relative risk for selected outcomes. She mentioned projects conducted to guide the protocol on assessment of child development, including:

- Pilot studies, for example, a study that addressed measures of spontaneous motor activity for behavioral assessment
- White papers addressing motor development, psychiatric assessments, neuropsychological assessments, and social-emotional development, and a lessons-learned paper on principles and practices of neurodevelopmental assessment in children
- Workshops addressing gene-environment interactions and the regulation of behavior and neurobehavioral development and environmental exposures.

Dr. Brenner noted that information on all these projects and their products is available on the Study Web site.

Dr. Brenner explained that the Study Plan, which was published as part of the Request for Proposals in November 2004, outlines the general study design of the National Children's Study. The purpose was to guide offerors so that they were better able to develop their proposals. The Study Plan outlines the schedule of visits and outlines the domains of measurement.

Dr. Brenner presented a chart with the schedule of visits and noted that there will be 16 face-to-face contacts over the 21-year study period and that contacts will occur most frequently early in the Study. Contacts will occur either in the home or in the clinical setting. She emphasized that the timing of the visits is driven by hypotheses.

Dr. Brenner said that she hoped that the schedule for measures through age 18 months can be finalized soon. She noted that the schedule had been revisited with a neurodevelopment group that was just forming, and there had not been much discussion of changing the timing for the visits up to age 18 months, but there have been comments on later visits.

Other data collections will include additional home visits with each change of residence, additional remote data collections (mail, telephone, internet) every 3 months, and neighborhood measures.

Measurements will include:
- Questionnaires and interviews (with mother, father, child, others)
- Observational assessments (of child, child-parent interactions)
- Clinical and behavioral assessments.

Domains of child development include neurodevelopmental domains of motor development, sensory function, cognitive function, and social, emotional, and psychiatric function; other domains include physical growth, functional outcomes, and physiologic domains. The general approach will be to measure domains of child development over time using a standardized battery of assessments and use screens for specific conditions with positive screens followed up with more in-depth testing.

Dr. Brenner explained that the process of moving from Study Plan to protocol has involved work groups within the Program Office, which have developed a draft of developmental assessments. A working team has recently been formed that includes scientific staff from the Program Office and the Coordinating Center and will also include scientists from the Vanguard Centers. The goal is to make recommendations for developmental assessments from birth through 18 months of age by the end of January 2006.

Dr. Brenner discussed considerations for assessments, which include:
- Sensitivity to low level and subtle effects of exposures
- Instrument reliable, valid, and previously tested in an appropriate setting
- Established normative data
- Appropriate for a large scale study—feasible, acceptable
- Strengths with respect to longitudinal assessments (range of ages)
- Availability for different cultures, languages.

Finally, Dr. Brenner discussed the projected timeline for the development and review of Study protocol, which includes the following targets:
- January 2006 Recommendations for measurements and key non-measurement aspects of the protocol
- February 2006 Integration into a unified Study protocol
- March 2006 Submission for internal governmental reviews
- April 2006 Submission for peer review
- May 2006 Period of public comment

Discussion

Questions and comments from session participants addressed the following issues:

- *Whether the exams from ages 2 months to 18 months would be conducted in the home.* Dr. Brenner said yes and noted that the first clinical assessment for the child is at age 3.

- *Whether children from homes where English in not the primary language would be included and if the timeframes will be the same.* Dr. Brenner said yes, children who speak languages other than English and who come from bilingual homes will be included, and the timeframe for visits will be the same for all children. Dr. Yeargin-Allsopp added that a benefit of having a longitudinal study is to see whether children have delays. If the time of assessment is the same for all children, it will be possible to see language development at the next assessment.

- *Whether English will be the only language in which language skills will be assessed.* Dr. Brenner said that one consideration is whether an instrument has been used in different settings, and the Study will use such instruments where available. Otherwise, the Study will use translations or administer the test in the language spoken.

- *Power considerations in looking at the interactive effects of multiple exposures and underlying variations in susceptibility (such as with ADHD).* Dr. Brenner noted that the Study will have opportunities to look at such interactions.

Principles and Practices of Neurodevelopmental Assessment in Environmental Health: Lessons Learned from the Centers for Children's Environmental Health

Virginia Rauh, Sc.D., M.S.W., Columbia Center for Children's Environmental Health, Heilbrunn Center for Population and Family Health, Columbia University Mailman School of Public Health

Dr. Rauh noted that the Centers for Children's Environmental Health have been in operation since the late 1990s. This is a group of studies funding by NIEHS and EPA. She credited Kim Dietrich, Ph.D., who is the lead author on the lessons learned paper that was the basis for her presentation. She explained that the purpose of the presentation was to present some of the lessons learned in the conduct of prospective cohort studies by the Centers in the field of pediatric neurotoxicology. She planned to address both missteps and achievements, with the hope that the Centers' collective experience can help guide the planning and implementation of the Study.

Dr. Rauh said that each of the Centers for Children's Environmental Health included in this summary has designed and conducted a prospective cohort study to assess the neurodevelopmental risks associated with selected exposures. She presented a table summarizing the various cohort studies including major outcomes.

Dr. Rauh then discussed the experiences of the Centers related to the following areas:
- Timing and domains of assessment
- Biological plausibility
- Population factors
- Site factors
- Child factors

- Quality assurance and quality control
- Date safety and monitoring
- Sensitivity and specificity of measures.

Timing and Domains of Neurodevelopmental Assessment. Domains of interest included:
- Overall neurological status
- Sensorimotor skills
- Attention
- Memory
- Problem solving (executive functions, organization and planning)
- Visual-spatial and perceptual skills
- Speech and language abilities
- Behavioral problems and adaptive skills
- Global indices of intellectual attainment and academic achievement
- More experimental protocols (visual recognition memory, the autonomic nervous system).

Dr. Rauh presented a table showing contact points and assessments for the studies, which were similar to those for the Study, and a table showing neurodevelopmental assessment in the Children's Centers for the first five-year funding cycle.

Biological Plausibility. Dr. Rauh said that when selecting developmental assessment techniques, it is important to make sure that one is tapping into the intended potential mechanisms and to try to match an assessment or test with the biological insult or effect hypothesized. This is not easy to do, and one must rely on broad based tests. She highlighted the following examples of questions:
- Permeability of the immature blood-brain barrier of the fetus and young infant to the exposure?
- Is the fetus lacking in drug-metabolizing detoxification capacities for the exposure of interest and therefore especially vulnerable?
- Are the exposures linked with growth retardation and maturational delays *in utero*? If so, they are prime candidates for functional teratogenicity.
- Do the exposures contain hormonally active agents with potential to disrupt central nervous system regulation?

Population Factors. Dr. Rauh said that there were many things that the researchers found that they had to do to complete the assessments. She highlighted the following lessons learned:
- Tests that are culturally relevant and non-biased should be selected. Investigators can utilize tests that have been adapted for non-English speaking children and their families, but the inventory of instruments in other languages and dialects is still quite low.
- The caregiver should be asked what language is spoken at home. All assessments of non-English speaking children should be done by examiners who are bilingual, preferably with the language of the child as their native tongue.
- Piloting of previously translated tests in the population of interest is essential to determine their suitability. Some non-verbal tests have been considered to be culturally neutral, such as the Raven's Progressive Matrices, but even non-verbal tests may not be completely culturally

neutral if the skills needed to complete the task are outside of the cultural experience of the population being evaluated.

- Because not all children can be assessed exactly at the scheduled age, it will be essential to choose tests that allowed assessment over a wide age range.
- Population factors also affect the degree of confounding that exists in the data, thus affecting the ability to detect associations between exposures and neurodevelopment. The degree of confounding may be so great that, after statistical adjustment, the exposure variable(s) no longer account for any further unique (independent) variance in the neurobehavioral data.
- Confounding is not limited to correlations between chemical exposure and non-chemical covariables such as socioeconomic status, quality of child rearing, parental intelligence, among others. Populations may be exposed to a mixture of compounds that are also inter-correlated. This presents a statistical challenge when attempting to estimate the independent or combined additive or synergistic effects of multiple chemical exposures. The problem of confounding in environmental neuroepidemiology has led some to speculate about the advantages of studying chemical or drug exposures in lower risk populations for the purpose of reducing confounding and thus strengthening associations between measures of dose and disease (for example, Bellinger, 1995). For all studies in which confounding is anticipated, decisions will need to be made whether to address the problem in the design stage or to use statistical procedures for adjustment after the data are collected.

Site Factors. Dr. Rauh highlighted the following lessons learned related to site factors:

- The geographical dispersion of the population may make home or school testing the only practical option.
- Testing sometimes must take place in multiple sites to accommodate families and prevent loss to follow-up.
- Studies in large rural communities (for example, Berkeley Center's study of children in the Salinas Valley community) found it necessary to use a recreational vehicle in addition to the clinic site to reach families without any means of transportation. Many Centers emphasized the importance of finding an environment free of distractions for both the interviews and the assessments. All Centers found that attempting to conduct assessments in the home was nearly impossible; this was especially true for participants living in crowded conditions. Finding a standardized testing facility was absolutely essential, but did not completely eliminate distractions during assessments.
- When the mother is interviewed, it is important that no one else is present. For one Center, a number of fathers wanted to be present during the initial interviews. Because some of the information was very personal, there was concern that the mother would not answer honestly, and this was not permitted.
- If a child absolutely needs the security of a familiar caregiver, the examiner should seat the adult companion outside of the child's field of vision. It may be necessary to include time for the child to settle in and become comfortable with the tester. In addition, where possible, breaks for bathroom and snacks should be built in to the assessment so that they are a minimal disruption.

Child Factors. Dr. Rauh noted the following lessons learned related to child factors:

- The child should be in reasonably good health at the time of evaluation with no current infection (such as a severe upper respiratory infection or acute otitis media) likely to significantly affect performance.
- Medications should be recorded. It is important to clarify this with the parent before the assessment begins. A child who is too ill to respond appropriately to the demands of the examination should be rescheduled.
- Given that many neurodevelopmental testing procedures require normal sensory function, a vision and hearing screen should also precede the examination.
- The child's behavior and affect during the test session should be rated, including the child's response to examiner and test situation, attitude toward self and test performance, work habits and problem-solving style, motor functioning, visual and auditory acuity, oral communication, and mood.
- These data can be used as cofactors in analyses, but this may lead to over control.

Quality Assurance and Quality Control. Dr. Rauh discussed the following lessons learned:
- Ideally, a single examiner should be used at each site or center.
- The examiner should be experienced with the population, but it is not necessary for a doctoral level psychologist to administer most tests. Individuals with baccalaureate or master degrees in psychology with additional training in the standardized administration and scoring of neuropsychological tests can examine children enrolled in a study under professional supervision.
- The examiner should be blinded as to the group membership or exposure status of the child.
- If more than one examiner is used, comparability in training and technique should be explicitly checked and regularly monitored. In multi-center studies, examiner training should be standardized across sites and regular meetings and conference calls should be arranged to discuss issues of administration and scoring as they arise.
- Inter-examiner differences can be minimized by having the same trainer.
- Inter-examiner differences can be minimized by videotaping practice sessions to provide feedback to the trainee and assess the presence of any differences in adherence to standardized administration or style which may result in inter-examiner variability and measurement error.
- In studies spanning several years, monitoring of inter-examiner reliability and proficiency should be practiced at regular intervals.

Sensitivity and Specificity of Measures. Dr. Rauh recommended getting the psychometric properties of the test to be used from the literature and paying attention to that. She noted the following:
- Sensitivity of a measure is defined as the proportion with the abnormality that the test classifies as abnormal (that is, the proportion of true positives).
- Specificity of a measure is the proportion of normal that the test classifies as normal (that is, the proportion of true negatives).
- In the selection of neurodevelopmental measures, it is clearly advantageous to include tests that have the best possible prognostic value.

Data Safety and Monitoring. Dr. Rauh said that in some ways, this should be first. The needs of the children with developmental delays are very important, and the community advisory boards were very interested in these kinds of issues. It is important to have a consistent policy about communicating certain findings. She discussed the following points:

- There is an ethical responsibility that referral protocols are in place to deal with the needs of children who perform poorly in the course of their participation in the study.
- Criteria need to be established for referral before data collection begins.
- Because of better predictive validity of these tests at older ages, a more rigorous criterion may be used at older ages (for example, scores 3 standard deviations below the mean up to 24 months and 2 standard deviations afterwards).
- Referrals normally take place through the primary care provider with parental permission. All referral related contacts should be carefully documented and confidentiality closely guarded.
- Protocols must include quick scoring of assessment tests and screenings of questionnaires, and so forth, to ensure prompt and proper referral and/or treatment.
- To ensure adequate follow-up and treatment of the child, it is important that available resources in the local area are identified.
- Clear protocols for notifying participants when their exposures levels may be dangerous are needed.
- Development of protocols and guidelines must involve the community advisory board, so that participants and communities are comfortable with the level of risk and understand what kinds of information will be shared with them. Some exposures, such as lead, require reporting to public health authorities if participant exposures meet action levels.

Future Directions in Neurodevelopmental Assessment in the National Children's Study. Dr. Rauh noted the following methods, which might be useful for the Study.

- Computer-based experimental measures for children: Neurobehavioral evaluation system (Baker, et al. 1985). Use of computer-assisted tests has several advantages in that examiner effects are reduced and data collection and scoring is automated and objective. However, care must be exercised when applying these methods to populations that have little or no exposure to computers or similar kinds of automated systems.
- Psychobiological measures: Measures of autonomic nervous system, including heart rate and blood pressure, can identify children with high reactivity. Baseline or resting measures are compared to response measures during challenging or stressful tasks. Children are exposed to a battery of tasks during a standardized protocol while continuous measures of cardiovascular response are recorded.
- Neurobiologically based markers of development: A number of environmental studies of children have made use of electrophysiological techniques in assessing the effects of neurotoxicants on central nervous system function. Visual as well as auditory evoked potentials have been examined and in many cases have been found to be sensitive to environmental chemical exposures. Another promising area is the use of neuroradiological techniques such as magnetic resonance imaging (MRI).
- Gene-environment interactions in neurodevelopment. Power is an important consideration.

Discussion

Dr. Yeargin-Allsopp commented that the work of the Children's Environmental Health Centers was clearly a tremendous resource for the Study. She asked Dr. Dietrich if he would be willing to share any additional thoughts. Dr. Dietrich said that Dr. Rauh nicely summarized the work and that the Centers have a lot of years of experience studying children. He stressed that paying attention to the lessons learned as outlined would make the Study's job easier.

Session presenters responded to questions and comments from participants concerning the following issues:

- *Whether there will be time for adjunct studies to put in additional data collection.* Dr. Brenner responded that data collection will be done every 3 months, and these are seen as short (10 minutes) to get at acute events. A process for review of possible adjunct studies is being developed, and review of adjunct studies will address burden.

- *Whether developmental trajectories found by the Study will be used as references for the future and whether the Study might be too diverse.* Dr. Yeargin-Allsopp replied that for some outcomes, Study data will become the standard reference, but not for others. For some conditions, the numbers may not be large enough. For the Study, the exclusions may come in analysis. The Study will identify a large, diverse group. In the analytic stage, the Study may exclude groups of children with certain kinds of exposures or risk factors. But the beauty of the Study is the diversity and size of the sample.

- *The central nervous system as the organ of particular vulnerability.* Dr. Yeargin-Allsopp agreed and noted that there has always been a focus on developmental outcomes in Study planning.

- *Whether assessments will be videotaped.* Dr. Brenner said that Study planners have thought about that and related issues. The current thought is that some child assessments will be videotaped. These will be a resource when new hypotheses are developed and will be another type of data similar to biological specimens stored for future analysis. A participant commented that in some respects, storage of specimens and tapes will be an important result of the Study.

- *The recommendation for a single trainer for interviewers.* Dr. Rauh said that the actual method for the Study will be more complicated and elegant than for the Centers' studies. All the efforts to make the process more homogenous are to control error. She said that evaluators do not have to be highly educated. If training is adequate and there is a gold standard—by either trainer or training tapes—and reliability is checked regularly, there should not be a problem. It is important to choose people with experience in that population. The Centers found having a single trainer helpful. Dr. Dietrich commented that centralized training is possible and beneficial and a high rate of examiner reliability could be obtained with the strategies mentioned. Centralized training is needed for all examiners. He stressed that the resources must be built into the grants to do this. Otherwise, error can be extreme. Standardized training centers with people experienced in administration of these instruments

are needed. Dr. Yeargin-Allsopp mentioned CDC's experience with autism surveillance in 17 states, where the amount of time for training and maintaining reliability was underestimated.

Additional Participants

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